PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference J&J 2148-PCT	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/EP 03/10921	International filing date *(day/month/year)* 30.09.2003	Priority date *(day/month/year)* 30.09.2002
International Patent Classification (IPC) or both national classification and IPC A61K7/48		
Applicant JOHNSON & JOHNSON CONSUMER FRANCE S.A.S. et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 1 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
24.03.2004	21.07.2004
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Young, A Telephone No. +49 89 2399-7811

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP 03/10921

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-21 as originally filed

Claims, Numbers

1-6 filed with telefax on 02.07.2004

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-6
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-6
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-6
	No:	Claims	

2. Citations and explanations

see separate sheet

Re Item V:

1. The documents considered in the present processing are consecutively numbered D1-D5; this numbering results from the citations D1-D5 found in the International Search Report (ISR) of the corresponding PCT application. It will be adhered to in the rest of the procedure. The cited passage(s) for each citation will be considered unless otherwise specified.

2. Novelty

The subject-matter of claims 1-6 is considered novel over the cited prior art within the meaning of Article 33(2) PCT.
The subject-matter of claim 1 differs from D1 in the electrolytes. D1 does not disclose a derivative of ethanolamine or a Vitamin C salt.
Documents D2-D5 fail to disclose the combination of sclerotium gum and a copolymer selected from the group consisting of methyl vinyl ether/maleic anhydride copolymer and acryloyldimethyltaurate vinylpyrrolidone copolymer.

3. Inventive step

The subject-matter of claims 1-6 is considered to involve an inventive step as required by Article 33(3) PCT.

Document D2 is considered the closest prior art document since it discloses a thickening composition with sufficient storage stability even in the presence of water-soluble vitamins which may function as electrolytes.
Thus, it seems that D2 intends to solve the same problem as the application namely to provide thickening formulations containing ethanolamine or vitamin C having sufficiently long shelf life. In other words the application provides an alternative solution compared to D2.

The subject-matter of claim 1 differs from D2 in the presence of a copolymer selected from the group consisting of methyl vinyl ether/maleic anhydride copolymer and acryloyldimethyltaurate vinylpyrrolidone copolymer, whereas D2 discloses hydrophobically-modified acrylate or methacrylate copolymer.

Document D4 teaches generally the use of PVM/MA copolymer as a thickening agent out of a huge list of possible thickening agents. However, there is no clear indication for the skilled man to combine PVM/MA copolymer with sclerotium gum to solve the problem of the application.
Thus, it is considered that a skilled man is not prompted by D4 to modify the

solution of D2 in order to arrive at the invention.
Therefore, inventive step can be acknowledged for the subject-matter of claims 1-6.

New claims

1. A chemical composition comprising:
   (a) sclerotium gum;
   (b) a copolymer selected from the group consisting of methyl vinyl ether/ maleic anhydride copolymer and acryloyldimethyltaurate vinylpyrrolidone copolymer;
   (c) a suitable carrier; and
   (d) one or more electrolytes wherein the electrolyte is an effective amount of at least one topically acceptable salt of at least one ethanolamine derivative of formula I:

   $(R^1)(R^2)NCH_2CH_2OH$ (I),

   wherein in formula I, R^1 and R^2 independently represent hydrogen, C_{3-6} cycloalkyl or C_{1-6} alkyl, optionally substituted with hydroxyl, methoxy, oxo or formyl, and/or a Vitamin C salt.

2. The chemical composition according to claim 1 wherein component (b) comprises the ammonium salt of acryloyldimethyltaurate vinylpyrrolidone copolymer.

3. The chemical composition according to claim 1 or 2 wherein the ethanolamine of formula I is a mixed glycolate/citrate salt of dimethylethanolamine.

4. The chemical composition according to one of the preceding claims comprising:
   (a) from 0.005 to 3 %, in particular from 0.005 to 1 %, of sclerotium gum;
   (b) a from 0.005 to 3 %, in particular from 0.005 to 1 %, of a copolymer selected from the group consisting of PVM / MA crosspolymer and ammonium acryloyldimethyltaurate vinylpyrrolidone copolymer;
   (c) a suitable carrier; and
   (d) from 0.001 % to 5 %, in particular from 0.001 % to 3 %, further in particular from 0.005 % to 1.5 %, of one or more electrolytes.

5. A topical formulation comprising a composition as claimed in the preceding claims and further ingredients.

6. The topical formulation as claimed in claim 5 wherein the further ingredients comprise surfactants, emulsifiers, consistency factors, conditioners, emollients, skin caring ingredients, moisturizers, humectants, thickeners, lubricants, chelating agents, fillers, binding agents, anti-oxidants, preservatives, active ingredients, in particular dermatologically active ingredients, fragrances, dyes, and/or opacifying agents, provided that they are physically and chemically compatible with the other components of the composition.